JAN 19 2007

FLOWCARDIA, INC.

5) 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21CFR807.92.

510(k) Number K067868

Applicant Information

Date Prepared: **September 22, 2006**

Name and Address: **FlowCardia, Inc.**
745 N. Pastoria Avenue
Sunnyvale, CA 94085
Ph: (408) 617-0352

Contact Person: **Dustin Michaels, Director of RA/CR**
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Device Information

Classification: DQY
Trade Name: The CROSSER System
Common Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter, 74 DQY / 21 CFR 870.1250

Predicate Device

Safe Cross Radio Frequency Total Occlusion Crossing System manufactured by Intraluminal Therapeutics, Inc. (K032031)

Device Description

The CROSSER System consists of a re-usable electronic Generator, Foot Switch, high frequency Transducer, and single-use CROSSER 14 Catheter. The CROSSER 14 Catheter is connected to the electronic Generator through the Transducer. The Foot Switch is used to activate the system. The Generator and Transducer convert AC power into high frequency mechanical vibrations which are propagated through a Nitinol core wire to the stainless steel tip of the CROSSER 14 Catheter. The main

body of the catheter is constructed from Pebax and a hydrophilic coating which covers the distal 90cm of the catheter.

Technological Characteristics

The FlowCardia CROSSER System is substantially equivalent to the Intraluminal Therapeutics (ILT) Safe-Cross System in intended use. The design (or mode of operation) of the Safe-Cross Wire is similar to the CROSSER 14 Catheter in that it is intended to be delivered through standard coronary guide catheters to a vascular occlusion and then used to facilitate recanalization of the obstruction. Both have roughly the same working length (146cm vs. 175cm) and are designed to be compatible with standard percutaneous techniques and equipment. The devices are constructed from commonly used catheter materials and coated with a hydrophilic material for increased lubricity. Their radiopaque tips are used to visualize their location within the body.

The Safe-Cross and the CROSSER System both use an energy source to facilitate placement of devices beyond total occlusions. The Safe-Cross System uses RF energy for this purpose versus the CROSSER System which utilizes high frequency vibration. Despite the differences in both energy source and construction materials the intended and method of use are substantially equivalent.

Physical Test Data

Design analysis, bench, and biocompatibility testing were conducted according to the relevant guidance documents to demonstrate that the FlowCardia CROSSER System met the acceptance criteria and performed similarly to the predicate device. In addition to dimensional verification, the following functional tests were performed: Tensile Strength, Torque Strength, Torqueability, Tip Flexibility, Coating Adherence/Integrity, Biocompatibility, Bench top Simulated Efficiency, Catheter Fatigue Testing, Shelf Life and Package Integrity Testing.

Clinical Test Data

In addition to the physical test data above, clinical study of the FlowCardia CROSSER System demonstrated substantially equivalent safety and effectiveness.

Conclusion

Based upon device physical and clinical comparisons the CROSSER System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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FlowCardia, Inc.
c/o Mr. Dustin Michaels
Director of Regulatory Affairs and Clinical Research
745 N. Pastoria Avenue
Sunnyvale, CA 94085

Re: K062868
The CROSSER System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: January 11, 2007
Received: January 12, 2007

Dear Mr. Michaels:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): **K062868**

Device Name: **The CROSSER System**

Indications for Use:

The CROSSER System is indicated in coronary arteries to facilitate the intra-luminal placement of conventional guidewires beyond chronic total occlusions.

Prescription Use		Over-The-Counter Use
X (Part 21 CFR 801 Subpart D)	AND/OR	_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062868